

### **REMARKS**

Claims 45, 55, 65 and 76 have been canceled. Claim 42 has been amended to recite "photoreceptor cell" rather than "retina cell." Support for the amendment to claim 42 can be found throughout the specification and in canceled claim 76. Claims 46, 56 and 66 have been amended to incorporate the language from canceled claims 45, 55 and 65. Thus, no new matter is added by the amendments to the claims. After entry of this amendment, claims 42-44, 46-54, 56-64, 66-71 and 73-75 will be pending.

#### ***Rejections under 35 U.S.C. §112, first paragraph – scope of enablement***

The Examiner has rejected claims 42-71 and 73-76 under 35 U.S.C. §112, first paragraph as not enabled for proliferating all types of retinal cells, including photoreceptor cells. Although Applicants respectfully disagree, in the interest of furthering prosecution, the claims have been amended to recite "photoreceptor cells." Applicants respectfully submit that the amendments to the claims overcome this rejection.

The Examiner has also rejected claims 42-71 and 73-76 under 35 U.S.C. §112, first paragraph as not enabled because Applicants have not provided any guidance or working examples as to how to administer the compounds in order to treat the claimed disorder. Applicants respectfully traverse this rejection.

Applicants respectfully submit that preferred dosage ranges or modes of administration need not be provided for the invention to be enabled. It is routine for one of skill in the art to determine an appropriate dosage and route of administration for a drug. The fact that some experimentation may be required to determine the desired dosage and administration route does not render a claim non-enabled. "A considerable amount of experimentation is permissible, if it is merely routine." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Furthermore, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104 (Fed. Cir. 1985).

One of skill in the art knows that the dosage of a drug can vary depending on a variety of factors, such as the nature and severity of the condition, the application method, the formulation, the patient's health, the desired rate of healing and other factors routinely assessed by those of skill in the art. However, it is routine for a skilled artisan to determine an appropriate dose and route of administration, despite these many factors. In fact, because dosages for pharmaceutical compositions are known to vary depending on a variety of factors, it is a common and accepted practice to claim a biotech invention in terms of an "effective amount" of an ingredient or substance. *See*, M.P.E.P. §2173.05[c].

Applicants submit that the claimed invention is enabled for all dosages of compositions that will produce the claimed result (i.e., "in an amount sufficient to proliferate the photoreceptor cell.") Therefore, Applicants respectfully submit that the specific dosage need not be required for the claims to be enabled. Applicants therefore request withdrawal of this rejection.

***Rejections under 35 U.S.C. §112, first paragraph – new matter***

The Examiner has rejected claims 42-71 and 73-76 under 35 U.S.C. §112, first paragraph as introducing new matter by reciting amino acids 108-188 of SEQ ID NO:2. Applicants respectfully traverse.

Amino acids 108-188 of SEQ ID NO:2 correspond to the domain containing the 8 conserved cysteines. The conserved eight cysteine domain is discussed throughout the application. *See*, for example, page 2, lines 7-9; page 11, lines 15-17 and 26-30; page 53, lines 9-12; and Figures 3A-3B. Therefore, the recitation of amino acids 108-188 does not include new matter. Applicants therefore request withdrawal of this rejection.

***Rejections under 35 U.S.C. §112, second paragraph – indefiniteness***

Claims 42-71 and 73-76 were rejected under 35 U.S.C. §112, second paragraph as indefinite for reciting the phrase "to proliferate the [photoreceptor] cell." As suggested by the Examiner, claim 42 has been amended to recite "to proliferate [photoreceptor] cells." Applicants therefore request withdrawal of this rejection.

Claims 45, 46, 55, 56, 65 and 66 were rejected under 35 U.S.C. §112, second paragraph as confusing as it is allegedly "not clear how one would administer the VEGF compound if it weren't in a pharmaceutical composition." Applicants respectfully traverse.

Although Applicants disagree with this rejection, in the interest of furthering prosecution, claims 45, 55, and 65 have been canceled.

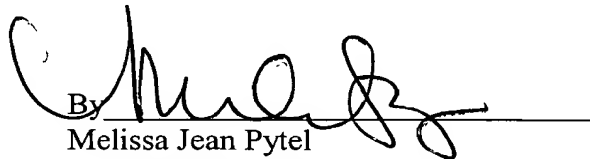
Applicants submit that the basis that has been provided for this rejection does not apply to claims 46, 56 or 66, which are all directed towards a sustained-release formulation. Pharmaceutical compositions other than sustained release formulations are known and can be routinely developed by the skilled artisan for administration of the VEGF compound. Applicants therefore request withdrawal of this rejection.

### **Conclusion**

The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application. Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

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Respectfully submitted,

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